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Notice of Independent Review Decision

[Date notice sent to all parties]:

04/13/2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: butrans patch 5 mcg/hr #4

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

Board Certified Anesthesiologist; Board Certified Pain Medicine

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

This patient is a female with complaints of pain. On 03/31/14, the patient was seen in clinic, and medications at that time included Tramadol and Cyclobenzaprine and Tylenol with Codeine. On 10/13/14, the patient was seen in clinic, and continued to have neck pain. Her Tramadol was discontinued and she was started on Butrans patch. On 01/21/15, the patient was seen back in clinic, and continued to describe neck pain. She was continued on Butrans patch.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

On 02/23/15, a utilization review report noted that Butrans was a medication that was not certified. It was noted the only referenced efficacy was the patient's subjective documentation of its prior efficacy and therefore the request was non-certified. On 03/20/15, a 2nd utilization review report noted that there was a lack of clinical documentation of opiate addiction or prior detoxification and/or hyperalgesia or neuropathic pain syndrome. Therefore the recommendation was for non-certification. Butrans may be used for addiction and/or chronic pain. If it is to be used for chronic pain, there should be documentation of a

hyperalgesia component to pain, patient with centrally acting mediated pain, or neuropathic pain and there should be documentation that the patient has previously been detoxified from other high use opiates. The records do not indicate the patient has been detoxified, and therefore the request for Butrans 5mcg per hour patch #4 is not medically necessary and the prior denials are upheld.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

☒ MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

☒ ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

Buprenorphine for chronic pain

Recommended as an option for treatment of chronic pain (consensus based) in selected patients (not first-line for all patients). Suggested populations: (1) Patients with a hyperalgesic component to pain; (2) Patients with centrally mediated pain; (3) Patients with neuropathic pain; (4) Patients at high-risk of non-adherence with standard opioid maintenance; (5) For analgesia in patients who have previously been detoxified from other high-dose opioids. Use for pain with formulations other than Butrans is off-label. Due to complexity of induction and treatment the drug should be reserved for use by clinicians with experience.

Drug description: Buprenorphine is a schedule-III controlled substance. Its mechanism of action is complex, involving four different opioid receptors at central and peripheral sites. It is primarily classified as a partial mu-agonist and kappa antagonist. It blocks effects of subsequently administered opioid agonists.

Proposed advantages of treatment: (1) An apparent antihyperalgesic effect (partially due to the effect at the kappa-receptor); (2) Ability to suppress opioid withdrawal; (3) Indications of safety for use in patients with renal impairment. There appears to be a ceiling effect for respiratory depression. (Johnson, 2005) (Koppert, 2005) (Pergolizzi, 2008) (Malinoff, 2005) (Landau, 2007) (Kress, 2008) (Heit, 2008) (Helm, 2008) (Silverman, 2009) (Pergolizzi, 2010) (Lee, 2011) (Rosenblum, 2012) (Daitch, 2012) (Colson, 2012) See also Opioid hyperalgesia.

Treatment of chronic pain: A waiver is not required for the off-label use of sublingual buprenorphine for the treatment of pain. An “X” should NOT be put before the DEA number. It is recommended that the words, “Chronic Pain Patient” and “Off-Label Use” be written on

the prescription. The most common use of buprenorphine formulations other than Butrans (such as Suboxone) for the treatment of chronic pain is for individuals who have a history of opioid addiction.

Use in opioid-experienced patient: There is the potential for buprenorphine to precipitate withdrawal in opioid-experienced patients.

Available formulations:

Buprenorphine hydrochloride injection (Buprenex®; generics available).

Buprenorphine hydrochloride sublingual tablets (Subutex® [innovator brand is off market]; generics available): 2 mg and 8 mg.

Buprenorphine hydrochloride and naloxone hydrochloride sublingual film (Suboxone®; no generics): Available as a film in doses of buprenorphine/ naloxone of 2mg/0.5mg, 4mg/1 mg, 8mg/2 mg and 12mg/3 mg. Tablet formulations are available as 2mg/0.5mg and 8mg/2mgs. Discontinuation of branded Suboxone sublingual tablets is to occur on 3/18/13, being replaced by the sublingual film described above.

Buprenorphine transdermal system (Butrans®; no generics): FDA-approved for moderate to severe chronic pain. Available as transdermal patches at 5mcg/hr, 10mcg/hr and 20mcg/hr.

See also Buprenorphine for treatment of opioid dependence.